

## I. Status of The Application

Claims 1-22 are pending.

Applicants acknowledge the finality of the Examiner's Restriction as applied to Applicant's election of Group IV (Claims 9-12, 17, 19, and 20) in Paper No. 8. Applicants further acknowledge and thank the Examiner for reconsidering and examining, along with the elected invention, the cell comprising the nucleic acid as recited in Claim 18 and the nucleic acid encoding the 312C2 peptide as recited in Claim 12. The other embodiments recited in Claims 12 and 18 are to be withdrawn by the Examiner as being drawn to non-elected inventions of Groups I and II, as set forth in the Office action dated 11-MAY-1998. Accordingly, Claims 9-12 and 17-20 were examined.

The specification was objected to under MPEP §608.01(V) allegedly for failing to capitalize trademark names (Nos. 6-7).

Claims 9-12 and 17-20 were rejected under §112, ¶2, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention (No. 9). Specifically:

- Claims 9-12 and 17-20 were alleged incomplete for dependence on non-elected Claim 1 (No. 10);
- Claims 9-12 and 17-20 were alleged indefinite for failure to use the sequence identifier after reciting "312C2" (No. 11);
- Claim 10 was alleged indefinite as it was unclear whether section a-d and e-f constituted a Markush group or whether section a-c and d-g constituted the Markush Group (No. 12);
- Claim 11 was alleged indefinite over recitation of the limitation "vector of Claim 9" as there was insufficient antecedent basis for this limitation (No. 13);
- Claim 17 was alleged indefinite over recitation of the phrase "expressing a nucleic acid" as it was unclear whether Applicants intend the protein expressed by the nucleic acid or the duplicate copies of the nucleic acid (No. 14);
- Claims 19 and 20 were alleged indefinite over recitation of the phrase "at least about" for rendering the degree of deviation from the recited percentage identity unclear (No. 15);
- Claims 19 and 20 were alleged indefinite over recitation of "% identity" as vague and indefinite for failing to allow one of ordinary skill in the art to determine the existence of gaps, or which mismatches, alterations or mutations are encompassed by the claims (No. 16);

Claim 19 was rejected under §102(a) as allegedly anticipated by Goldstein (WO 96/15272) and under §102(b) as allegedly anticipated by Matoba (U) or Matoba, et al., (GenBank Accession #D17247(V)) (Nos. 18-21). Consequently, Applicants acknowledge that the remaining claims are free of prior art.

## **II. The Invention**

The present invention is based, in part, upon the discovery of a family of polypeptides that appear to act as a costimulator of T cell activation. In particular, the invention provides mammalian, e.g., rodent and primate, polynucleotide sequences that are expressed in the thymus, and are induced on T cells and spleen cells following activation.

## **III. The Amendments**

The specification has been amended to the to correct an erroneous format for referring to a trademark.

Claims 9-12, and 17-20 have been amended to advance and expedite prosecution by better placing the application in condition for allowance. New Claims 23-43 have been added to more particularly point out and distinctly claim the subject matter of the present invention. Certain typographical changes have been made to ensure proper antecedent basis and consistency in terminology.

Support for amending previous Claims 9-12, and 17-20 and for adding new Claim 23-43 can be found throughout the specification.

For example, support for reciting amino or nucleotide residues and specific sequence identifiers (such as in amended Claims 9, 10, 19, and 20 and new Claims 27, 29(b), 30, 32, and 33) can be found in the sequence listing for SEQ ID NO: 1-4, e.g., at pages 63-72; page 19, lines 6-16 and at page 20, lines 25-36.

Support for species, allelic and other variants as in Claims' 30(b-c), can be found, e.g., at page 19, line 37, bridging to page 20, line 7; and at page 22, lines 10-13. Support for detectable labeling or synthetically producing the polypeptide of the invention can be found, e.g., at page 12, lines 9-13; and at page 32, lines 3-20.

Support for expression of the polypeptide of the invention on activated T cells and for binding polyclonal antibodies generated against the polypeptides of the invention can be found, e.g., at page 2, lines 21-27; page 3, lines 1-5; page 49, lines 31-34; at page 33, lines 6-16; and page 18, lines 24-36.

Support for reciting the degeneracy of the genetic code as in new Claim 28(b) can be found, e.g., at page 7, lines 10-36.

Support for reciting natural sequences, as in new Claims 24(a-c), 30(b), and 39(b) can be found, e.g., at page 3, lines 15-16.

Support for reciting conservative substitutions, as in new Claim 24(d-e), 30(a), and 39(a) can be found, e.g., at page 7, line 10, bridging to page 8, line 21.

Support for reciting sequence residues to the extracellular, transmembrane, and intracellular domains of SEQ ID NO: 2 or 4 as in Claim 10(a) or 10(d) can be found, e.g., at page 4, lines 13-16; and at page 20, lines 25-36.

Support for the hybridization conditions of amended Claim 9 and new Claims 23, 25, 30, 31, 37, 38(a), and 39 can be found, e.g., page 37, lines 16-29.

Support for reciting duplex formation as in Claims 26, 33, and 34 can be found, e.g., page 15, lines 3-5; or for reciting detectable labeling can be found, e.g., page 27, lines 8-9; and page 32, lines 3-20.

Support for the production of an antigenic polypeptide as in Claims 17, 27(d), 36, 38(b), and 42 can be found, e.g., at page 29, line 36, bridging to page 32, line 30; and page 33, lines 6-16.

Support for reciting the polynucleotide of the invention in vectors and host cells as in Claims 11, 18, 34-35, and 40-41 can be found, e.g., page 4, lines 18-19; page 12, line 35, bridging to page 13, line 4; and page 38, line 14, bridging to page 40, line 2.

Support for reciting kits as in Claim 12 can be found, e.g., page 46, line 21, bridging to page 50, line 14.

Applicants believe that the amendments and the newly presented claims are fully supported and introduce no new matter. For the convenience of the Examiner, the proposed claims are attached in Appendix A. Applicants respectfully request examination of the newly added claims. Applicants believe no new issues are raised in the pending claims.

Applicants previously paid for 3 independent and 22 total claims. The newly proposed claims number 3 independent and 29 total claims. Accordingly, new claim fees have been calculated on the transmittal accompanying this amendment, however, should the calculation be in error, authorization is granted the Commissioner to charge or credit the appropriate amounts to the DNAX Research Institute Deposit Account No: 04-1239.

#### **IV. The Non-Art Rejections and Objections**

##### **A. The Specification**

Applicants have amended the specification to properly recite listed trademarks. Accordingly, Applicants respectfully request withdrawal of the objection.

##### **B. §112, Rejections**

Claims 9-12 and 17-20 were rejected under §112, ¶2, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention (Nos. 9-16). Applicants respectfully traverse the rejections.

To advance and expedite prosecution, Applicants have amended the claims by:

- (1) shifting all previous claim dependencies from Claim 1 to newly amended Claim 9, including all the previous limitations of Claim 1;
- (2) expressly reciting specific sequence identifiers (i.e., particular SEQ ID NOS.) where appropriate;
- (3) dividing Claim 10 into two distinct claims having separate Markush groups;
- (4) amending Claim 11 to correct a lack of antecedent basis;
- (5) amending Claim 17 to clarify that the claim encompasses the protein expressed; and
- (6) eliminating language reciting "percentage identity" that might be interpreted to 'read on' gaps in potentially claimed sequences; and
- (7) positively reciting that "sequence identity" equals "complete identity" (i.e., 100% identical) over at least a minimum number of contiguous amino or nucleotide residues that have specific sequence identifiers (i.e., unique SEQ ID NOS.).

Therefore, one of ordinary skill in the art would have no trouble defining the metes and bounds of the amended claims.

Applicants believe the presently amended claim language cures the Office Action's objections and rejections by better placing the claims in condition for allowance. Additionally, the presently adopted claim language is definite, commensurate in scope with the specification, and does not add new matter. Accordingly, Applicants respectfully request withdrawal of the rejections.

## V. The Art Rejections and Objections

### A. §102, Rejections

Claim 19 was rejected under §102(a) as allegedly anticipated by Goldstein (WO 96/15272) and under §102(b) as allegedly anticipated by Matoba (U) or Matoba, et al., (GenBank Accession #D17247(V)). (Nos. 18-21).

Applicants respectfully traverse the rejections.

Specifically, Matoba (V) was alleged to teach a 98 bp sequence having 79.6% identity to SEQ ID NO: 3 and Goldstein (WO 96/15272) allegedly taught a 52 bp sequence (SEQ ID NO: 73) having a 96.3% identity to SEQ ID NO: 3.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration" *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990), *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983), and MPEP §2131. Therefore, to anticipate a claim, the cited reference must teach each and every element of the claim under consideration.

Previously, Applicants' Claim 19 recited a nucleic acid having 70% identity to at least 30 nucleotides of SEQ ID NO: 3. Now, Applicants' amended Claim 19 recites:

A recombinant or isolated polynucleotide of Claim 9, that encodes at least 15 contiguous residues of SEQ ID NO: 4.

Neither Goldstein (WO 96/15272) nor Matoba (U) or Matoba, et al., (GenBank Accession #D17247(V)) recite a nucleic acid encoding a polypeptide encoding at least 15 contiguous amino residues of SEQ ID NO: 4. Therefore, neither Goldstein (WO 96/15272) nor Matoba (U) or Matoba, et al., (GenBank Accession #D17247(V)), anticipate by failing to recite each and every element of Claim 19. Accordingly, Applicants respectfully request withdrawal of the rejections.

## VI. Summary

For all the reasons set forth herein, Applicants maintain that objections and/or the rejections to: (1) the specification for allegedly failing to comply with MPEP §608.01(V); (2) Claims 9-12 and 17-20 for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention; and (3) Claim 19 for allegedly being anticipated, are overcome and should be withdrawn.


### Conclusion

Applicants maintain that presently amended and newly added claims (Claims 9-12, 17-20, and 23-35; Appendix A) clearly and patentably define the invention. Accordingly, Applicants respectfully request reconsideration and passage of the pending claims to allowance at the earliest possible convenience.

Applicants believe the present amendments and response to the objections and/or rejections raised in the 14-SEP-1998 Office Action represent a complete, timely, and good faith response to all the issues raised therein. Should the Examiner deem that allowance is not appropriate, Applicants respectfully request an interview be granted with the undersigned representative to discuss the issues. If the Examiner would like to discuss any point raised in the Office Action, Applicants' representative may be reached at (650) 496-1244.

Respectfully submitted,

Dated: March 15, 1999

  
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Enclosures and attachments:

Appendix A- Proposed claims as of March 1999

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